

Food and Drug Administration, HHS

§ 73.2500

pH (30 percent solution weight to volume at 25 °C), not less than 4.7 and not more than 5.8.

Arsenic (as As), not more than 3 parts per million.

Lead acetate, not less than 99 percent.

Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* The color additive lead acetate may be safely used in cosmetics intended for coloring hair on the scalp only, subject to the following restrictions:

(1) The amount of the lead acetate in the cosmetic shall be such that the lead content, calculated as Pb, shall not be in excess of 0.6 percent (weight to volume).

(2) The cosmetic is not to be used for coloring mustaches, eyelashes, eyebrows, or hair on parts of the body other than the scalp.

(d) *Labeling requirements.* (1) The label of the color additive lead acetate shall conform to the requirements of § 70.25 of this chapter, and bear the following statement or equivalent:

Wash thoroughly if the product comes into contact with the skin.

(2) The label of the cosmetic containing the color additive lead acetate, in addition to other information required by the act, shall bear the following cautionary statement, conspicuously displayed thereon:

CAUTION: Contains lead acetate. For external use only. Keep this product out of children's reach. Do not use on cut or abraded scalp. If skin irritation develops, discontinue use. Do not use to color mustaches, eyelashes, eyebrows, or hair on parts of the body other than the scalp. Do not get in eyes. Follow instructions carefully and wash hands thoroughly after each use.

(e) *Exemption for certification.* Certification of this color additive for the prescribed use is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[45 FR 72117, Oct. 31, 1980, as amended at 72 FR 10357, Mar. 8, 2007]

§ 73.2400 Pyrophyllite.

(a) *Identity and specifications.* The color additive pyrophyllite shall conform in identity and specifications to

the requirements of § 73.1400 (a)(1) and (b).

(b) *Uses and restrictions.* Pyrophyllite may be safely used for coloring externally applied cosmetics, in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The labeling of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to all applicable requirements of law, including the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.2496 Mica.

(a) *Identity and specifications.* The color additive mica shall conform in identity and specifications to the requirements of § 73.1496(a)(1) and (b).

(b) *Uses and restrictions.* Mica is safe for use in coloring cosmetics generally, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification pursuant to section 721(c) of the act.

[42 FR 38561, July 29, 1977]

§ 73.2500 Silver.

(a) *Identity.* (1) The color additive, silver, is a crystalline powder of high purity silver prepared by the reaction of silver nitrate with ferrous sulfate in the presence of nitric, phosphoric and sulfuric acids. Polyvinyl alcohol is used to prevent the agglomeration of crystals and the formation of amorphous silver.

(2) Color additive mixtures of silver may contain only those diluents listed

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in § 73.1001(b) and, in addition, nitrocellulose.

(b) *Specifications.* Silver shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 5 parts per million.

Mercury (as Hg), not more than 1 part per million.

Silver (as Ag), not less than 99.9 percent.

(c) *Uses and restrictions.* The color additive silver may be safely used for coloring fingernail polish at a level not to exceed 1 percent of the final product.

(d) *Labeling.* The color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any other information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[44 FR 65974, Nov. 16, 1979]

§ 73.2575 Titanium dioxide.

(a) *Identity and specifications.* The color additive titanium dioxide shall conform in identity and specifications to the requirements on § 73.575 (a)(1) and (b).

(b) *Uses and restrictions.* The color additive titanium dioxide may be safely used in cosmetics, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any other information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 721(c) of the act.

21 CFR Ch. I (4–1–12 Edition)

§ 73.2645 Aluminum powder.

(a) *Identity and specifications.* The color additive aluminum powder shall conform in identity and specifications to the requirements of § 73.1645 (a)(1) and (b).

(b) *Uses and restrictions.* Aluminum powder may be safely used in coloring externally applied cosmetics, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification pursuant to section 721(c) of the act.

[42 FR 38563, July 29, 1977]

§ 73.2646 Bronze powder.

(a) *Identity and specifications.* The color additive bronze powder shall conform in identity and specifications to the requirements of § 73.1646 (a)(1) and (b).

(b) *Uses and restrictions.* Bronze powder may be safely used in coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of the color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 33724, July 1, 1977]

§ 73.2647 Copper powder.

(a) *Identity and specifications.* The color additive copper powder shall conform in identity and specifications to the requirements of § 73.1647 (a)(1) and (b).